



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: EFED's Response to "Comments From Cheminova A/S on EPA's Draft Preliminary Risk Assessments for Malathion"

TO: Betty Shackleford, Product Manager 53 and
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Special Review and Reregistration Division , 7808C

FROM: Norman Birchfield, Ph.D.
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THROUGH: Arnet Jones, Chief Environmental Risk Branch I
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Secondary Review: Kevin Costello

EFED's responses to errors in the *Preliminary Risk Assessment for Malathion* identified by Cheminova A/S are itemized below. EPA requested that Cheminova A/S provide comments only on typographical, computational, mathematical, or other similar errors. All errors identified by Cheminova were addressed. In a few cases it was necessary to make slight adjustments to estimated environmental concentrations (resulting in small changes to risk quotients). None of these corrections however resulted in significant changes to EFED's risk assessment. Also ambiguities in application rates used in the assessment were identified, however, none of the ambiguities resulted in a substantial change to the risk assessment. Criticisms from Cheminova A/S as to how the risk assessment was performed (along with other comments) will be addressed after the public comment period.

1. CHEMINOVA A/S: Cheminova believes that EFED has inappropriately extrapolated information obtained from the use of malathion in the boll weevil and Medfly eradication programs, and adult mosquito control (a human health use) for conducting its environmental risk assessments. Cheminova does not consider these programs to be representative of typical agricultural practice; these uses are special programs directed by government agencies that include use patterns (general area applications using ULV formulations) that are not

representative of general agricultural practices. Cheminova believes that it is inappropriate for EPA to draw general conclusions from these special uses about the potential for malathion to contaminate ground water, surface waters, and drinking water from typical agricultural uses. Rather, EPA should conduct risk assessments for each of these special programs separate from typical agricultural uses.

EFED RESPONSE: This criticism does not fall within the category of typographical, computational, mathematical, or other similar errors but will be addressed by EFED during the upcoming public comment period.

2. CHEMINOVA A/S: EFED has conducted its ecological risk assessment using a use rate for cotton that includes up to 25 applications per year. Cheminova notes that the 25 applications per year are included on labels to accommodate the boll weevil eradication program. Typical agricultural use of malathion includes no more than 8 applications per year (3 early season and up to 5 late season applications). USDA notes that after the boll weevil is eradicated, the use of all insecticides (including malathion) on cotton will be reduced to three or fewer applications per year. Cheminova believes that EFED should conduct an ecological risk assessment based on how malathion is typically used in general agriculture rather than for a use pattern meant for the boll weevil eradication program and believes that EFED should work with USDA concerning potential risks associated with the Boll Weevil eradication program.

EFED RESPONSE: This criticism does not fall within the category of typographical, computational, mathematical, or other similar errors but will be addressed by EFED during the upcoming public comment period.

3. CHEMINOVA A/S: On page 6 of the EFED chapter, EFED states that all technical malathion produced in the U.S. is manufactured by Cheminova. This statement is inaccurate. Cheminova does not produce any technical malathion in the U.S.; it is produced in Denmark and shipped to the U.S.

EFED RESPONSE: This statement has been corrected. "Produced" was replaced by "marketed"

4. CHEMINOVA A/S: Page 8 of the EFED chapter is a blank page.

EFED RESPONSE: This possibly occurred in transfer. EFED had no blank page on our copy of the chapter.

5. CHEMINOVA A/S: Cheminova confirms that it holds one Federal registration of a mixture formulation of malathion and methoxychlor (EPA Registration No. 67760-2). However, this formulation is not currently marketed or sold in the United States.

EFED RESPONSE: Corrected to reflect that Cheminova and Platte Chemical Company

manufacture the mixture and that only Platte Chemical Co. markets the mixture in the U.S. This label was included in the SMART package given to the Agency.

6. CHEMINOVA A/S: Cheminova believes that risk assessments should only be performed for the use patterns being supported for reregistration. Once the final RED is issued, EPA should take appropriate steps to assure that product labeling is amended to reflect only those use patterns approved for reregistration.

EFED RESPONSE: Since this reregistration is not specific to Cheminova products only, but also those of the other 63 formulators, the other labeled uses from malathion products have been considered by EFED.

7. CHEMINOVA A/S: The following crops are not listed in EFED's Table 1: Brussel sprouts, cantaloupe, cauliflower, collards, kale, kohlrabi, peppermint, and trefoil. Cheminova assumes that cantaloupe is covered by melons. According to the residue chemistry section of EPA's document, the maximum supportable use rates for these crops, based on available residue data, are 1.25, 1.0, 1.25, 1.25, 1.25, 1.25, 0.94, and 1.25 lbs ai/A, respectively.

EFED RESPONSE: EFED has made corrections to the tables for all listed crops except trefoil. Cantaloupe would be considered under melons. Trefoil was not located in the use information provided by the registrant during the SMART meeting, but is assumed to be under similar use pattern as clover. The use information provided by the registrant had listed some of the omitted crops above kohlrabi but it was not clear they were applied at same rates etc.

8. CHEMINOVA A/S: In Table 1, EFED has written "pepper and spearmint". Cheminova assumes that EFED means "peppermint and spearmint". This is easily mistaken to mean peppers rather than peppermint. EPA should clarify this point.

EFED RESPONSE: Cheminova is correct- The tables have been corrected.

9. CHEMINOVA A/S: In Table 1, EFED lists a maximum application rate of 1.25 lbs ai/A for chayote root and chayote fruit. However, according to the residue chemistry section of EPA's document, the maximum supportable use rate, based on available residue data, is 1.5 lbs ai/A.

EFED RESPONSE: EFED originally placed the crop in 1.25 lb ai/A by error. This value has been corrected to 1.88 lbs a.i./acre based on the SMART report submitted by Cheminova A/S.

10. CHEMINOVA A/S: In Table 1, EFED lists a maximum application rate of 0.94 lbs ai/A for mushrooms. However, according to the residue chemistry section of EPA's document, the maximum supportable use rate, based on available residue data, is 1.7 lbs ai/A.

EFED RESPONSE: The application rate in the EFED assessment was based on the SMART

book rate of 0.02 lbs ai/1000 sq. ft. Using a slightly higher corrected rate suggested by Cheminova A/S will not affect ecological risk since mushrooms are mostly an indoor crop.

11. CHEMINOVA A/S: In Table 1, EFED lists a maximum application rate of 1.0 lbs ai/A for squash. However, according to the residue chemistry section of EPA's document, the maximum supportable use rate, based on available residue data, is 1.0 lbs ai/A for winter squash and 1.88 lbs ai/A for summer squash.

EFED RESPONSE: Page 7 of the SMART book lists only squash at 0.9375 and no delineation between types of squash was noted. However the table will be corrected to reflect winter squash at the 1.0 lb rate.

12. CHEMINOVA A/S: In Table 1, EFED lists a maximum application rate of 1.25 lbs ai/A for sweet potatoes. However, according to the residue chemistry section of EPA's document, the maximum supportable use rate, based on available residue data, is 1.56 lbs ai/A.

EFED RESPONSE: EFED has moved sweet potato to 1.56 lbs ai/A next to potato.

13. CHEMINOVA A/S: EFED included the use of malathion on ornamental lawns, turf, and golf courses. As noted in its March 10, 1998, letter to EPA, Cheminova is not supporting this use for reregistration. Thus, EPA should delete this use from its risk assessments.

EFED RESPONSE: See response to question 6.

14. CHEMINOVA A/S: In its description of the environmental fate of malathion, EFED compares the results of registrant submitted guideline studies to results from studies obtained from the open literature. EFED presents the information from the open literature in such a way that it appears to give equal weight to the results from the open literature studies. Cheminova believes that the registrant-submitted, guideline studies, conducted in compliance with Good Laboratory Practices and conducted with Cheminova's test material, should be given much more weight than studies from the open literature. If EFED wants to include information from the open literature, it should fully evaluate these studies, provide data evaluation records for these studies, identify discrepancies and ambiguities and seek to eliminate them by follow up with the study authors, determine the availability of underlying raw data, and include a discussion of the problems and uncertainties associated with these studies like it does with the registrant submitted studies.

EFED RESPONSE: This criticism does not fall within the category of typographical, computational, mathematical, or other similar errors but will be addressed by EFED during the upcoming public comment period.

15. CHEMINOVA A/S: In its discussion about spray drift on page 26, EFED indicated that in 1998 it planned to complete its evaluation of the studies conducted and submitted by the Spray

Drift Task Force. If EFED has completed this review, it should update this section of the document.

EFED RESPONSE: EFED has changed 1998 to 2000.

16. CHEMINOVA A/S: In the Pesticide Root Zone Model (PRZM) files provided by EFED to Cheminova, two errors were found for the citrus scenario. First, there was an application date of June 31st for each year in the scenario. The date was changed to June 30th, but the final result for the scenario was unchanged. Additionally, the value for the K_{oc} was not entered correctly. The correct value is 151 ml/g, but PRZM was reading the value as 15 ml/g in the EPA scenario. These errors should be corrected.

EFED RESPONSE: EFED acknowledges that Koc values in the PRZM input files for the Florida citrus scenario were off-set one digit resulting in the correct value of 151 being read as 15. Higher Koc values are expected to result in lower runoff. The input values were corrected and the model was rerun. The corresponding RQs were also changed in the aquatic risk quotient tables to reflect this change.

The old results were

Max rate:	peak = 162 ppb,	60d average = 11.1ppb
Typical rate:	peak = 47.3 ppb,	60d average = 2.59 ppb

The new results are:

Max rate:	peak = 156 ppb,	60d average = 10.7 ppb
Typical rate:	peak = 42.6 ppb,	60d average = 2.33 ppb

The small difference resulting from correcting the Koc values has no effect on the estimated ecological risks associated with malathion use.

17. CHEMINOVA A/S: EFED states that malathion has been implicated in numerous fish kill incidents over its five decades of use. EFED needs to provide references for this statement. Furthermore, if the references cited by EFED do not demonstrate that malathion is the cause of these incidences, then EFED should not cite these references.

EFED RESPONSE: The sentence containing the word "implicated" has been changed to "Those which are associated with malathion use in the area of the kills are summarized below along with factors which are known about events preceding the incident." The table in the RED chapter only lists aquatic incidents which were reported as associated with the use of malathion, and each includes an evaluation of the likelihood that the incident was caused by exposure to malathion.

EFED will provide more detailed citations for all of the incidents listed in the RED chapter.